

**FISH & NEAVE****FACSIMILE TRANSMISSION**

TO	COMPANY/FIRM	RECIPIENT FAX	RECIPIENT PHONE
Ms. Margaret Stevens	USPTO Group 1645	703.308.4407	703.305.3608

SENDER	DATE	SENDER'S FAX	SENDER'S PHONE
Lorraine Coke	September 30, 2003	650.566.4175	650.617.4055

CLIENT	RE:	TIME	PAGES (INCLUDING COVER)
002344.0004	Application No. 09/864,761 Our Ref.: AEOMICA-X-1		

**MESSAGE****\*\*\*\*URGENT\*\*\*\***

Dear Ms. Stevens:

We filed a reply to office action by certified mail on June 30, 2003. PTO confirmed receipt of the reply on July 2, 2003. However, the reply has not been entered into the PTO database. Enclosed are copies of the stamped return postcard and original documents as filed for your reference.

I phoned the OIPE to check the status of this reply and they have no record of receiving the documents. If a new copy of the documents need to be resubmitted by mail, please notify me as soon as possible.

Please enter the reply into the USPTO records.

Thank you very much for your quick attention.

Lorraine Coke  
Patent Assistant

This communication is intended only for the use of the addressee and may contain information that is privileged and confidential. If you are not the intended recipient, you are hereby notified that the unauthorized dissemination of the communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone. If not completely received, please call back at 212.598.9300 as soon as possible.

825 UNIVERSITY AVENUE, PALO ALTO, CA 94301 TEL 650.817.4000 FAX 650.617.4080  
1251 AVENUE OF THE AMERICAS, NEW YORK, NY 10020 TEL 212.598.9000 FAX 212.598.9080  
1899 PENNSYLVANIA AVENUE, WASHINGTON, DC 20006 TEL 202.303.2400 FAX 202.303.2480

BP-25-03 02:20 FROM FISH AND NEAVE

DOCKET NO. AFOMICA-X-1  
 CONFIRMATION NO. 6802  
 APPLICANTS Poon et al:  
 APPLICATION NO. 09/864,761 FILED May 23, 2001

RECEIPT IS HEREBY ACKNOWLEDGED OF THE  
 Transmittal Letter (in duplicate); Reply to April 9, 2003 Office Action; copy of Executed  
 Declaration filed May 23, 2001; copy of Application Data Sheet filed May 23, 2001; copy  
 of Filing Receipt for US 60/207,456; copies of three (3) acknowledgment postcards; CD-R  
 containing copy of priority document, US 60/207,456 including specification, drawings,  
 sequence listing, and ten (10) tissue tables.

DATED June 30, 2003



MAILED IN CONNECTION WITH THE ABOVE CASE.

COMMISSIONER FOR PATENTS

DOCKET NO.

AEOMICA-X-1

CONFIRMATION NO.

6802

APPLICANTS Penn et al.

APPLICATION NO. 09/864,761

FILED.

May 23, 2001

RECEIPT IS HEREBY ACKNOWLEDGED OF THE

Transmittal Letter (in duplicate); Reply to April 9, 2003 Office Action; copy of Executed Declaration filed May 23, 2001; copy of Application Data Sheet filed May 23, 2001; copy of Filing Receipt for US 60/207,456; copies of three (3) acknowledgment postcards; CD-R containing copy of priority document, US 60/207,456 including specification, drawings, sequence listing, and ten (10) tissue tables.

DATED

June 30, 2003

FILED IN CONNECTION WITH THE ABOVE CASE.

COMMISSIONER FOR PATENTS

REV. 9/01  
For Other Than A Small Entity

Docket No. AEOMICA-X-1

Applicants : Penn et al.

Application No. : 09/864,761 Confirmation No.: 6802

Filed : May 23, 2001

For : HUMAN GENOME-DERIVED SINGLE EXON NUCLEIC  
ACID PROBES USEFUL FOR GENE EXPRESSION  
ANALYSIS

Group Art Unit : 1631

Examiner : Cheyne Dune Ly

Palo Alto, CA 94301  
June 30, 2003

Mail Stop Non-Fee Amendment  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith:

- [X] a Reply to April 9, 2003 Office Action;
- [X] a copy of Executed Declaration filed on May 23, 2001;
- [X] a copy of Application Data Sheet filed on May 23, 2001;
- [X] a copy of Filing Receipt for priority document, US 60/207,456, filed on May 26, 2000;
- [X] copies of three (3) acknowledgment postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4, 2002, confirming the PTO's receipt of Information Disclosure Statements filed in the application;
- [X] CD-R containing a true and correct copy of priority document, US 60/207,456, as filed on May 26, 2000, including specification, drawings, sequence listing, and ten (10) tissue tables.

FEE FOR ADDITIONAL CLAIMS

☒ A fee for additional claims is not required.

☐ A fee for additional claims is required.

The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEES
TOTAL CLAIMS	15	- 92	* = 0	X \$ 18 =	\$
INDEPENDENT CLAIMS	1	- 11	** = 0	X \$ 84 =	\$
FIRST PRESENTATION OF A MULTIPLE DEPENDENT CLAIM				+ \$280 =	\$

\* If less than 20, insert 20.

TOTAL

\$

\*\* If less than 3, insert 3.

☐ A check in the amount of \$\_\_\_\_\_ in payment of the filing fee is transmitted herewith.

☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. § 1.16, in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

☐ Please charge \$\_\_\_\_\_ to Deposit Account No. 06-1075 in payment of the filing fee. A duplicate copy of this transmittal letter is transmitted herewith.

EXTENSION FEE

☐ The following extension is applicable to the Response filed herewith; ☐ \$110.00 extension fee for response within first month pursuant to 37 C.F.R. § 1.136(a); ☐ \$410.00 extension fee for response within second

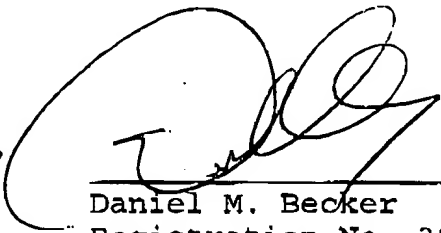
month pursuant to 37 C.F.R. § 1.136(a); [ ] \$930.00 extension fee for response within third month pursuant to 37 C.F.R. § 1.136(a); [ ] \$1,450.00 extension fee for response within fourth month pursuant to 37 C.F.R. § 1.136(a); \$1,970.00 within fifth month pursuant to 37 C.F.R. § 1.136(a).

[ ] A check in the amount of [ ] \$110.00; [ ] \$410.00; [ ] \$930.00; [ ] \$1,450.00; [ ] \$1,970.00 in payment of the extension fee is transmitted herewith.

[X] The Director is hereby authorized to charge payment of any additional fees required under 37 C.F.R. § 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

[ ] Please charge the [ ] \$110.00; [ ] \$410.00; [ ] \$930.00; [ ] \$1,450.00; [ ] \$1,970.00; extension fee to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

30 JUNE 2003

  
Daniel M. Becker

Registration No. 38,376

Attorney for Applicants

FISH & NEAVE

1251 Avenue of the Americas

New York, New York 10020-1105

Tel.: (650) 617-4000

I hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to: **COMMISSIONER FOR PATENTS, P.O. BOX 1450, Alexandria, VA 22313-1450** on:

6-30-03  
Date of Deposit  
Lorraine Cole  
Name of Person Signing  
[Signature]  
Signature of Person Signing  
6-30-03  
Date of Signature

PATENTS

Attorney Docket No. AEOMICA-X-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

Applicants : Penn et al.  
Application No. : 09/864,761 Confirmation No.: 6802  
Filed : May 23, 2001  
For : HUMAN GENOME-DERIVED SINGLE EXON  
NUCLEIC ACID PROBES USEFUL FOR GENE  
EXPRESSION ANALYSIS  
Group Art Unit : 1631  
Examiner : Cheyne Dune Ly

Palo Alto, CA 94301  
June 30, 2003

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

Sir:

In response to the Office Action mailed April 9,  
2003, Applicants submit the following amendments and remarks.  
Applicants also enclose herewith:

1) Copy of Declaration for instant application, filed on May 23, 2001.

2) Copy of Application Data Sheet for instant application, filed on May 23, 2001.

3) Copy of Filing Receipt for priority document, US 60/207456, filed on May 26, 2000.

4) Copies of acknowledgement postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4, 2002, confirming the PTO's receipt of Information Disclosure Statements with cited documents for the instant application.

5) CD-R containing a true and correct copy of priority document, US 60/207456, as filed on May 26, 2000, including specification, drawings, sequence listing, and ten (10) tissue tables.



## IN THE SPECIFICATION:

The following amendments are made pursuant to "Amendments In A Revised Format Now Permitted", 1267 Off. Gaz. Pat. Office 106 (February 25, 2003).

Please replace the title, beginning at page 1, line 1 of the specification, with the following rewritten title:

~~-- HUMAN GENOME DERIVED SINGLE EXON NUCLEIC ACID PROBES USEFUL FOR GENE EXPRESSION ANALYSIS METHODS FOR MANUFACTURING CUSTOMER-DESIGNED SINGLE EXON MICROARRAYS --~~

Please replace the paragraph beginning at page 1, line 7, with the following rewritten paragraph:

-- This application is a continuation-in-part of International Application No. PCT/US01/00666, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00667, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00664, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00669, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00665, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00668, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00663, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00662, filed January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00661, filed

January 30, 2001; is a continuation-in-part of International Application No. PCT/US01/00670, filed January 30, 2001; ~~claims priority under 35 U.S.C. § 365(e) to international patent application nos. PCT/US01/00666, PCT/US01/00667, PCT/US01/00664, PCT/US01/00669, PCT/US01/00665, PCT/US01/00668, PCT/US01/00663, PCT/US01/00662, PCT/US01/00661, PCT/US01/00670,~~ all filed January 30, 2001, claims the benefit of priority under 35 U.S.C. § 119(e) to provisional applications for United States Patent serial nos. 60/180,312, filed February 4, 2000, U.S. Provisional Application No. 60/207,456, filed May 26, 2000, U.S. Provisional Application No. 60/234,687, filed September 21, 2000, and U.S. Provisional Application No. 60/236,359, filed September 27, 2000; claims priority under 35 U.S.C. § 119(a) to GB 24263.6, filed October 4, 2000; is a continuation-in-part of U.S. Application No. 09/608,408, filed June 30, 2000; is a continuation-in-part of U.S. Application No. 09/632,366, filed August 3, 2000, which claims the benefit of U.S. Provisional Application No. 60/180,312, filed February 4, 2000, and U.S. Provisional Application No. 60/207,456, filed May 26, 2000; and is a continuation-in-part of U.S. Application No. 09/774,203, filed January 29, 2001, which is a continuation-in-part of U.S. Application No. 09/608,408, filed June 30, 2000, is a continuation-in-part of U.S. Application No. 09/632,366, filed August 3, 2000, claims the benefit of U.S. Provisional Application No. 60/180,312, filed February 4, 2000, U.S. Provisional Application No. 60/207,456, filed May 26, 2000, U.S. Provisional Application No. 60/234,687, filed September 21, 2000, and U.S. Provisional Application No. 60/236,359, filed September 27, 2000, and claims priority under

~~35 U.S.C. § 119(a) to GB 24263.6, filed October 4, 2000, and is a continuation in part of United States patent application serial nos. 09/608,408, filed June 30, 2000, 09/632,366, filed August 3, 2000, and 09/774,203, filed January 29, 2001, the disclosures of which are incorporated herein by reference in their entirety.~~

Please replace the paragraph beginning at page 91, line 32, with the following rewritten paragraph:

--Identification can be effected by comparing the genomic sequence returned by query 20 with public or private databases containing known repetitive sequence, vector sequence, artificial sequence, and other artifactual sequence. Such comparison can readily be done using programs well known in the art, such as CROSS\_MATCH or REPEATMASKER, the latter available on-line at the University of Washington Genome Center web site ~~http://ftp.genome.washington.edu/RM/RepeatMasker.html~~, or by proprietary sequence comparison programs the engineering of which is well within the skill in the art.--

Please replace the paragraph beginning at page 159, line 11, with the following rewritten paragraph:

--For purposes herein, percent identity of two nucleic acid sequences is determined using the procedure of Tatiana et al., "Blast 2 sequences - a new tool for comparing protein and nucleotide sequences", *FEMS Microbiol Lett.* 174:247-250 (1999), which procedure is effectuated by the

computer program BLAST 2 SEQUENCES, available online at the  
National Center for Biotechnology Information (NCBI) website.

~~<http://www.ncbi.nlm.nih.gov/blast/bl2seq/bl2.html>~~ --

## IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application, pursuant to "Amendments In A Revised Format Now Permitted", 1267 Off. Gaz. Pat. Office 106 (February 25, 2003).

Listing of Claims:

1 - 109. (canceled)

110. (currently amended) A method of manufacturing a microarray that has single exon probes that share at least one customer-identified attribute in common, comprising:

receiving data from a customer that identify at least one ~~desired~~ common probe attribute;

identifying within a database a plurality of single exon probes having the customer-~~desired~~-identified probe attribute; and then

addressably disposing said identified probes on a support substrate capable of functioning in microarray hybridization experiments,

wherein at least 50% of the probes addressably disposed on said microarray are single exon probes that include a fragment of no more than one exon of a eukaryotic genome, said fragment selectively hybridizable at high stringency to an expressed gene, wherein said plurality of nucleic acid probes averages at least 100 bp in length, and wherein said eukaryotic genome averages at least one intron per gene.

111. (previously added) The method of claim 110, wherein at least 95% of the nucleic acid probes addressably disposed on said microarray include a selectively hybridizable portion of no more than one exon of said eukaryotic genome.

112. (previously added) The method of claim 110, wherein at least 50% of the single exon nucleic acid probes addressably disposed on said microarray further comprise, contiguous to a first end of said fragment, a first intronic and/or intergenic sequence that is identically contiguous to said fragment in the genome.

113. (previously added) The method of claim 110, wherein at least 95% of said single exon nucleic acid probes addressably disposed on said microarray further comprise, contiguous to a first end of said fragment, a first intronic and/or intergenic sequence that is identically contiguous to said fragment in the genome.

114. (previously added) The method of claim 110, wherein at least 50% of said single exon nucleic acid probes addressably disposed said microarray further comprise, (i) contiguous to a first end of said fragment, a first intronic and/or intergenic sequence that is identically contiguous to said fragment in the human genome, and (ii) contiguous to a second end of said fragment, a second intronic and/or intergenic sequence that is identically contiguous to said fragment in the human genome.

115. (previously added) The method of claim 110, wherein at least 95% of said single exon nucleic acid probes addressably disposed said microarray further comprise, (i) contiguous to a first end of said fragment, a first intronic and/or intergenic sequence that is identically contiguous to said fragment in the human genome, and (ii) contiguous to a second end of said fragment, a second intronic and/or intergenic sequence that is identically contiguous to said fragment in the human genome.

116. (previously added) The method of claim 110, wherein at least 50% of said single exon nucleic acid probes addressably disposed said microarray lack prokaryotic and bacteriophage vector sequence.

117. (previously added) The method of claim 110, wherein at least 95% of said single exon nucleic acid probes addressably disposed said microarray lack prokaryotic and bacteriophage vector sequence.

118 - 119. (withdrawn)

120. (previously added) The method of claim 110, wherein said eukaryotic genome averages at least two introns per gene.

121. (previously added) The method of claim 110, wherein said eukaryotic genome averages at least three introns per gene.

122. (previously added) The method of claim 110, wherein said eukaryotic genome averages at least five introns per gene.

123. (previously added) The method of claim 110, wherein said genome is a human genome.

124. (previously added) The method of claim 110, wherein said steps of receiving customer data and identifying within a database are performed by a digital computer.

125. (currently amended) The method of claim 124, wherein each of said addressably disposed single exon probes comprises a nucleotide sequence selected from the group consisting of exon SEQ ID NOs: set forth in Tables 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13, and the complete complements thereof, and each of said single exon probes hybridizes under high stringency conditions to a nucleic acid molecule expressed in human cells or tissues.

126. (previously added) The method of claim 125, wherein each of said addressably disposed single exon probes comprises a nucleotide sequence selected from the group consisting of exon SEQ ID NOs: set forth in Table 5.

127 - 130. (withdrawn)



**REMARKS**Status of the claims

Claims 59-130 are pending.

Claims 59 - 109, 118, 119, and 127 - 130 have been withdrawn from consideration.

Claims 110 - 117 and 120 - 126 stand rejected, and claims 59 - 130 are subject to restriction and/or election requirement.

Applicants herein cancel claims 59 - 109 to non-elected restriction groups without prejudice to applicants' prosecuting these claims or claims of similar scope in one or more continuation or divisional applications.

Priority

According to the Examiner, priority document, US 60/207,456, filed on May 26, 2000, has been marked lost by the US Patent and Trademark Office ("PTO").<sup>1</sup> Pursuant to the Examiner's request, applicants provide herewith a copy of the Filing Receipt for priority document US 60/207,456, documenting the filing of this application in the PTO on May 26, 2000. Applicants also provide, as a courtesy to the Examiner, an electronic copy of US 60/207,456, as filed, on CD-R, which would otherwise occupy over 1200 pages of printed text.

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<sup>1</sup> Applicants note that this document is also a priority document for several PCT International Applications and is one of several such documents that have recently been transmitted to the International Bureau of WIPO. It is therefore possible that the missing document is currently in the PCT Division of the PTO.

The Examiner notes that in order to obtain priority under 35 U.S.C. 119(e) or 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. The Examiner further notes that for the benefit of priority under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This information should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

Applicants respectfully submit that claims for priority were properly included in the instant application, as filed.

The first sentence of the application recited a complete list of the priority documents. In addition, the Declaration (see enclosed copy), filed as part of the instant application on May 23, 2001, provided the status of the prior U.S. applications and the prior PCT applications designating the U.S. to which priority was claimed. Finally, the Application Data Sheet (see enclosed copy), filed as part of the instant application on May 23, 2001, contained the above information, as well as the relationships between the instant application and the prior-filed copending nonprovisional applications and international applications designating the United States.

All of the necessary information was thus submitted during the pendency of the application and within the later of four months from the actual filing date of the application or

sixteen months from the filing date of the prior application as required by 37 C.F.R. § 1.78(a)(2)(ii) and (a)(5)(ii) for a utility application filed under 35 U.S.C. 111(a) on or after November 29, 2000.

However, in order to simplify the entry of the benefit claims into the PTO's computer database, applicants have amended the first sentence of the specification to include all of the information contained in the Declaration and Application Data Sheet as filed in a form compliant with the PTO's notice dated 26 February 2003 ("Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. §§ 119(e), 120, 121, and 365(c)").

#### IDS

The Examiner indicates that the instant application file lacks the documents listed on the Information Disclosure Statements, paper no. 5, entered December 3, 2001, paper no. 7, entered August 23, 2002, and paper no. 9, entered October 4, 2002. Applicants enclose herewith copies of acknowledgement postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4, 2002, respectively, indicating that copies of the listed documents were indeed received by the PTO for the instant application. As a courtesy, Applicants will hand-deliver replacement copies of these documents to the Examiner. Applicants respectfully request that the Examiner acknowledge consideration of the cited references prior to allowance of any claims by return of initialed copies of the accompanying Form PTO-1449s.

OBJECTIONS

The Examiner objects to the presence of an embedded hyperlink and/or other form of browser-executable code in the disclosure. References to hyperlinks in the specification have been amended to provide instead a description of the organization hosting the relevant web sites.

The Examiner objects that the title of the invention is not descriptive. The title has been amended to make it descriptive of the invention as presently claimed.

REJECTIONS35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112, ¶ 2 for being vague and indefinite with respect to the term "desired". Applicants have amended claim 110 to remove this term and respectfully request that this rejection be withdrawn.

The Examiner has rejected claim 125 and its dependent claim 126 under 35 U.S.C. § 112, ¶ 2 for being vague and indefinite with respect to the phrase "the complements thereof". Applicants submit that the amendment of claim 125 to read "the complete complements thereof" overcomes this rejection and respectfully request that the claim rejection be withdrawn.

35 U.S.C. § 101

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 101 for lack of patentable utility.

The claims are drawn to methods for manufacturing a microarray that has single exon probes that share at least one customer-identified attribute. Because applicants do not understand the Examiner to mean that methods of manufacturing demonstrably useful products - nucleic acid microarrays - lack utility, applicants believe that the rejection is not addressed to the invention as presently claimed, and thus respectfully request that it be withdrawn.

35 U.S.C. § 112, ¶ 1 Enablement

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112 ¶ 1 for lack of enablement, based on the corresponding rejection of these claims under 35 U.S.C. § 101 for lack of utility.<sup>2</sup> Because the § 101 rejection is in error for the reasons advanced above, applicants respectfully request that the rejection for lack of enablement be withdrawn.

35 U.S.C. § 112, ¶ 1 Written Description

The Examiner has rejected claims 110-117 and 120-126 under 35 U.S.C. § 112, 1 for lack of written description. The Examiner argues that the specification provides insufficient written description to support the genus encompassed by at

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<sup>2</sup> The Examiner quotes from the background section of the disclosure that "identification of functional genes from genomic data remains, however, an imperfect art" and argues that one skilled in the art would not know how to predictably use the claimed invention without undue experimentation. As applicants noted with respect to the § 101 rejection, this argument does not appear to be addressed to the invention as presently claimed.

least claims 125 and 126 and that, except for the elected species (SEQ ID NO:17240), the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides.

The pending claims are drawn to methods of manufacturing a microarray. The claims require, among other things, that "at least 50% of the probes addressably disposed on said microarray are single exon probes that include a fragment ... selectively hybridizable at high stringency to an expressed gene". In claim 125, as amended, each of the addressably disposed probes must comprise "a nucleotide sequence selected from the group consisting of exon SEQ ID NO:s set forth in Tables 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 and the complete complements thereof", and further that each of the probes "hybridizes under high stringency conditions to a nucleic acid molecule expressed in human cells or tissues".

Applicants submit that the specification of the instant application sufficiently describes the claimed invention. As noted recently by the Federal Circuit, "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (quoting *Guidelines for Examination of Patent Applications*

Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001)).

Complete structures are provided in the instant specification for all of the nucleotide sequences set forth in Tables 4 - 13, and one of skill in the art could readily determine structures for "the complete complements thereof". Moreover, the specification provides on p. 78 an explicit definition of the term "high stringency conditions" for purposes of solution phase and microarray-based hybridizations. Example 9 of the training materials accompanying the PTO's Revised Interim Written Description Guidelines describes a situation in which the claim language required high stringency hybridization. According to the analysis for that example, "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention."

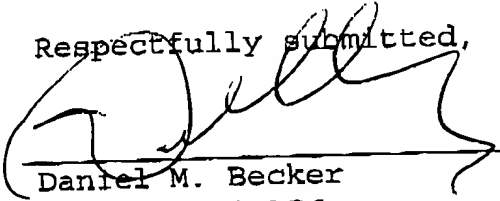
Applicants submit that, as was the case in Example 9 of the training materials, the instant specification provides disclosure adequate to support the claimed invention. They therefore respectfully request withdrawal of the rejection for lack of written description.

CONCLUSION

Applicants respectfully submit that claims 110 - 117 and 120 - 126, all of the claims now pending, are free of rejection or objection. Applicants thus respectfully submit that the claims are in good and proper form for allowance, and respectfully request the same.

If the Examiner believes that any issues remain outstanding, Applicants respectfully request that the Examiner call the undersigned for a telephonic interview.

Respectfully submitted,

  
Daniel M. Becker  
Reg. No. 38,376  
Attorney for Applicants

I hereby Certify that this  
Correspondence is being  
deposited with the U.S.  
Postal Service as First  
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COMMISSIONER FOR PATENTS,  
P.O. BOX 1450, Alexandria,  
VA 22313-1450 on:

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Lorraine Coke  
Name of Person Signing  
[Signature]  
Signature of Person Signing  
6-30-03  
Date of Signature

FISH & NEAVE  
Customer No. 1473  
1251 Avenue of the Americas  
New York, New York 10020-1105  
Tel.: (650) 617-4000  
Fax: (212) 596-9090

Enclosures

- 1) Copy of Declaration for instant application, filed on May 23, 2001.
- 2) Copy of Application Data Sheet for instant application, filed on May 23, 2001.
- 3) Copy of Filing Receipt for priority document, US 60/207456, filed on May 26, 2000.
- 4) Copies of acknowledgement postcards, date-stamped by the PTO November 30, 2001, August 23, 2002, and October 4,



2002, confirming the filing and receipt of Information Disclosure Statements with cited documents for the instant application.

5) CD-R containing an electronic copy of priority document, US 60/207456, as filed on May 26, 2000.

Sep-30-2003 11:15am From-FISH & NEAVE

6506174053

T-778 P.026/046 F-616

AEOMICA\_X\_1

DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

HUMAN GENOME-DERIVED SINGLE EXON NUCLEIC ACID PROBES USEFUL  
FOR GENE EXPRESSION ANALYSIS

the specification of which

(check [X] is attached hereto  
one)

[ ] was filed on \_\_\_\_\_ as  
Application Serial No. \_\_\_\_\_ and  
was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I do not know and do not believe that the invention was ever patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application.

I do not know and do not believe that the invention was in public use or on sale in the United States of America more than one year prior to this application.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below, and hereby claim the benefit under 35 U.S.C. § 365(c) of any PCT international application(s) listed below which designated the United States of America, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or PCT application designating the United States in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. Application(s)

<u>09/774,203</u>	<u>January 29, 2001</u>	<u>pending</u>
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
<u>09/632,366</u>	<u>August 3, 2000</u>	<u>pending</u>
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
<u>09/608,408</u>	<u>June 30, 2000</u>	<u>pending</u>
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

Prior PCT Application(s) Designating the U.S.

			<u>Pending</u>	
<u>PCT/US01/00666</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00667</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00664</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00669</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00665</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

<u>PCT/US01/00668</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00663</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00662</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00661</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
<u>PCT/US01/00670</u>	<u>PCT</u>	<u>30 January 2001</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim priority benefits under Title 35, United States Code, § 119(a) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate, if any, having a filing date before that of the application on which priority is claimed, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior foreign application for patent in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application::

Prior Foreign Application(s)

Priority  
Claimed

<u>0024263.6</u>	<u>GB</u>	<u>04 October 2000</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim priority benefits under Title 35, United States Code, § 119(e) of any provisional applications for United States patent listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior provisional application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known by me to be material to patentability as

defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior Provisional Application(s)

			Priority Claimed
<u>60/180,312</u> (Number)	<u>US</u> (Country)	<u>04 February 2000</u> (Day/Month/Year Filed)	[X] [ ] Yes No
<u>60/207,456</u> (Number)	<u>US</u> (Country)	<u>26 May 2000</u> (Day/Month/Year Filed)	[X] [ ] Yes No
<u>60/234,687</u> (Number)	<u>US</u> (Country)	<u>21 September 2000</u> (Day/Month/Year Filed)	[X] [ ] Yes No
<u>60/236,359</u> (Number)	<u>US</u> (Country)	<u>27 September 2000</u> (Day/Month/Year Filed)	[X] [ ] Yes No

As a named inventor, I hereby appoint the following attorneys or agents to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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First Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

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Second Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

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Third Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

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T-778 P.033/046 F-616

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 Citizenship Country:: US

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 1473  
Fax One:: 212.596.9090

## APPLICATION INFORMATION

Title Line One:: HUMAN GENOME-DERIVED SINGLE EXON NUCLEIC  
Title Line Two:: ACID PROBES USEFUL FOR GENE EXPRESSION  
Title Line Three:: ANALYSIS  
Total Drawing Sheets:: 10  
Formal Drawings?:: Yes  
Application Type:: Utility  
Docket Number:: AEOMICA\_X\_1  
Secrecy Order in Parent Appl.?:: No

## REPRESENTATIVE INFORMATION

Representative Customer Number:: 1473  
Registration Number One:: 38376  
Registration Number Two:: 34408  
Registration Number Three:: 46234

## CONTINUITY INFORMATION

This application is a:: NON PROV. OF PROVISIONAL  
> Application One:: 60/180312  
Filing Date:: 02-04-2000

This application is a:: NON PROV. OF PROVISIONAL  
> Application Two:: 60/207456  
Filing Date:: 05-26-2000

This application is a:: NON PROV. OF PROVISIONAL  
> Application Three:: 60/234687  
Filing Date:: 09-21-2000

This application is a:: NON PROV. OF PROVISIONAL  
> Application Four:: 60/236359  
Filing Date:: 09-27-2000

This application is a:: CONTINUATION IN PART OF  
> Application Five:: 09/774203  
Filing Date:: 01-29-2001

This application is a:: CONTINUATION IN PART OF  
> Application Six:: 09/632366  
Filing Date:: 08-03-2000

This application is a:: CONTINUATION IN PART OF  
> Application Seven:: 09/608408  
Filing Date:: 06-30-2000

This application is a:: CONTINUATION IN PART OF  
> Application Eight:: PCT/US01/00666  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Nine:: PCT/US01/00667  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Ten:: PCT/US01/00664  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Eleven:: PCT/US01/00669  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Twelve:: PCT/US01/00665  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Thirteen:: PCT/US01/00668  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Fourteen:: PCT/US01/00663  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Fifteen:: PCT/US01/00662  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Sixteen:: PCT/US01/00661  
Filing Date:: 01-30-2001

This application is a:: CONTINUATION IN PART OF  
> Application Seventeen:: PCT/US01/00670  
Filing Date:: 01-30-2001

#### PRIOR FOREIGN APPLICATIONS

Foreign Application One:: 00242636  
Filing Date:: 10-04-2000  
Country:: GB  
Priority Claimed:: Yes

Source:: PrintEFS Version 1.0.1

Sep-30-2003 11:17am From-FISH & NEAVE

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T-778 P.037/046 F-616



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/207,456	05/26/2000		150	MDhMORF- 2P	10		

CONFIRMATION NO. 7880

## FILING RECEIPT

1473  
FISH & NEAVE  
1251 AVENUE OF THE AMERICAS  
50TH FLOOR  
NEW YORK, NY 10020-1105

OC000000006018021

Date Mailed: 04/27/2001

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Sharron G. Penn, San Mateo, CA;  
David R. Rank, San Francisco, CA;  
David K. Hanzel, Palo Alto, CA;

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MAY 03 2001

If Required, Foreign Filing License Granted 04/27/2001

FISH &amp; NEAVE - PATENT DEPT.

REFERRED TO DMS  
NOTED BY \_\_\_\_\_

Projected Publication Date: N/A

Non-Publication Request: No

Early Publication Request: No

## Title

Human genome-derived single exon nucleic acid probes useful for gene expression analysis  
by microarray

Data entry by : BERSOMA, GENET

Team : OIPE

Date: 04/27/2001



**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

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**PLEASE NOTE the following information about the Filing Receipt:**

- The articles such as "a," "an" and "the" are not included as the first words in the title of an application. They are considered to be unnecessary to the understanding of the title.
- The words "new," "improved," "improvements in" or "relating to" are not included as first words in the title of an application because a patent application, by nature, is a new idea or improvement.
- The title may be truncated if it consists of more than 500 characters (letters and spaces combined).
- The docket number allows a maximum of 25 characters.
- If your application was submitted under 37 CFR 1.10, your filing date should be the "date in" found on the Express Mail label. If there is a discrepancy, you should submit a request for a corrected Filing Receipt along with a copy of the Express Mail label showing the "date in."
- The title is recorded in sentence case.

Any corrections that may need to be done to your Filing Receipt should be directed to:

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T-778 P.040/046 F-616

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Office of Initial Patent Examination  
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Washington, DC 20231



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T-778 P.041/046 F-616

Docket No. AEOMICA\_X\_1

Applicant Penn et al.

Serial No. 09/864,761 Filed May 23, 2001

*Receipt is hereby acknowledged of the*  
Transmittal Letter in Duplicate; Information Disclosure  
Statement; Form PTO-1449 in Duplicate; Three Hundred and  
Fifty Three (353) References

Dated November 30, 2001

*Filed in connection with the above case.*

COMMISSIONER OF PATENTS  
AND TRADEMARKS

Docket No. AEOMICA\_X\_1

Applicant Penn et al.

Serial No. 09/864,761 Filed May 23, 2001

*Receipt is hereby acknowledged of the*  
Transmittal Letter in Duplicate; Information Disclosure  
Statement; Form PTO-1449 in Duplicate; Three Hundred and  
Fifty Three (353) References

Dated November 30, 2001

*Filed in connection with the above case.*

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Dr. 1045  
CM 1/7

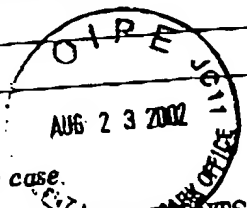
Applicant Penn et al.  
 Serial No. 09/864,761 Filed May 23, 2001  
 Docket No. AEOMICA-X-1

*Receipt is hereby acknowledged of the*  
Transmittal Letter in Duplicate; Reply to June 24, 2002  
Office Action; Supplemental Information Disclosure Statement;  
Form PTO-1449 in Duplicate; Eight (8) References; Check in  
the Amount of \$110.00

Dated August 19, 2002

*Filed in connection with the above case.*

COMMISSIONER OF PATENTS  
 AND TRADEMARKS



Applicant Ann et al.

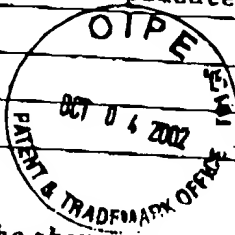
Docket No. AEOMICA-X-1

Serial No. 09/864,761

Filed May 23, 2001

*Receipt is hereby acknowledged of the*  
Transmittal Letter in Duplicate; Supplemental Information  
Disclosure Statement; Form PTO-1449 in Duplicate;  
Fifty Two (52) References

Dated October 2, 2002



*Filed in connection with the above case.*

COMMISSIONER OF PATENTS  
AND TRADEMARKS

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